

## REMARKS

The Abstract has been objected to as being vague. Specifically, the Official Action avers that the absence of structural formula I leaves the Abstract vague for failure to provide the generic formula which define the radicals set forth therein.

Applicants have amended the Abstract to incorporate formula I therein. In addition, applicants have also included structural formulae II. In view of the finality of the restriction requirement, the recitation of structural formulae III-V, which have been deemed representative of separate inventions, have been deleted from the Abstract.

The characterization of the specification as a continuation is the subject of an objection. Specifically, the Official Action indicates that the inclusion of the meaning of M as being (C\_24O) indicates new matter which puts into question of the characterization of the present application as a continuation. This meaning of M is not included in the parent application.

As discussed below, Claim 1 has been amended to delete the recitation that M is (C\_24O). As such, the implication that the present application is a continuation-in-part application is rebutted. That meaning has been deleted in favor of the meaning (C-O). That meaning appears in the originally filed specification of which the present application is a continuation. Attention is directed to Page 3, line 22 of the specification where the amended meaning of M in Claim 1 is provided.

Two of the original claims, Claims 3 and 4, have been withdrawn from consideration as being directed to separate inventions. The nine remaining claims, examined on the merits in this application, Claims 1, 2 and 5-11, stand objected to as embracing non-elected subject matter. Specifically, the Official Action avers that the retention of the four meanings of R<sub>1</sub>

embraces non-elected subject matter. That is, of the meanings of R<sub>1</sub> in original Claim 1 three of them, the radicals denoted as III, IV, and V, are directed to non-elected subject matter. As such, only the formula II is within the scope of the elected invention given the making final of the restriction requirement imposed in the present application.

Applicants have amended Claims 1, 2, 5 and 11 to delete the meanings of R<sub>1</sub> embodied by structural formulae III, IV and V. As such, the objection to Claims 1, 2 and 5-11 are overcome.

Applicants reserve their right to file a divisional application, during the pendency of the present application, directed to the subject matter deleted from the claims of the present application.

Of the nine claims examined on the merits, seven of them have been rejected on formal grounds. Applicants have amended these claims and respectfully submit that all the claims currently in this application are patentable over the rejection of record.

The seven claims subject to rejection, Claims 1, 2, 5 and 7-10, stand rejected on formal grounds, under 35 U.S.C. §112, second paragraph, as being indefinite for a plurality of reasons.

The first indefiniteness ground of rejection has been considered above. That is, the third meaning of M, (C<sub>24</sub>O) is not only not supported by the specification and but is not a known chemical radical. The inclusion of this meaning was an obvious typographical error. That meaning has been deleted from Claim 1.

Applicants have replaced the deleted meaning of M with (C-O). That meaning, carbonyl, is well established in the chemical arts and is fully supported by the originally filed specification, *supra*.

The second ground of indefiniteness of the claims subject to rejection is predicated upon the recitation, in Claim 1, from which Claim 2, 5 and 7-10 each depend, of structural formula XVII. Specifically, the Official Action avers that the optional double bond between N and M is required, rather than being optional. That is, unless there is a double bond at that position the nitrogen atom includes only two bonds, which is impossible.

Applicants have amended Claim 1 so that the radical having the structural formula XVII includes an optional positive charge. As such, the impossibility of too many bonds associated with meanings (C-O) and N for radical M is overcome. That is, in the case where there is an optional double bond between M and the nitrogen atom in formula XVII and M is (C-O) or N, that radical has a positive charge.

Applicants argue that the addition of a positive charge adds no new matter to the claims or to the specification, at Page 2, lines 14 to 33, insofar as that amendment corrects an obvious typographical error. The correction of an obvious typographical error, such as the absence of an optional positive charge, adds no new matter when the remainder of the application is consistent with the correction. It is well established that the correction of an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of error in the application but also its appropriate correction. In re Oda, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971).

The third ground of indefiniteness imposed in the Official Action is predicated upon the meaning of variables A to G, I to L and Z, in radicals XV to XVII, being nitrogen. Radicals XV and XVII are recited as being meanings of R<sub>4</sub> and R<sub>5</sub> in Claim 1. Since those radicals are uncharged those aromatic rings cannot be nitrogen because that would result in those radicals having a positive charge.

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The fourth related ground of indefiniteness is directed to the meanings, in Claim 1, of R<sub>4</sub> and R<sub>5</sub>. These meanings, oxygen, sulfur or carbonyl, for G, I, J and K in structural radical XVI, the Official Action argues, are impossible given the requirement that radical XVI is predicated upon tetravalent bondings therefor.

Applicants have overcome the third and fourth grounds of indefiniteness by adding an optional positive charge to radicals XV and XVI in the event that these radicals do not have the meaning carbon. Applicants submit that these amendments add no new matter to the specification and the claims for the same reason that the amendment of radical XVII adds no new matter.

The fifth ground of indefiniteness is predicated upon the Official Action view that the radical having structural formula XVI is impossible insofar as it is a five membered ring. The Official Action states that aromatic rings with five membered rings having a negative charge.

Applicants concede that the Official Action observation is meritorious. Therefore, they have added an second bond to ring atom L in structural formula XVI. Applicants strongly urge that the addition of this second bond to L in radical XVI of Claim 1 adds no new matter to the application. This is another correction of an obvious error appreciated by those skilled in the art. It is noted that the specification, at Page 2, lines 15 to 30, has been similarly amended to conform to this amendment in the claims.

The sixth ground of indefiniteness is imposed due to the recitation, in Claim 1, of meanings of R<sub>2</sub> being substituted or unsubstituted C<sub>1</sub>-C<sub>6</sub> alkenyl or substituted or unsubstituted C<sub>1</sub>-C<sub>6</sub> alkynyl. These meanings have been amended so that the lower limit of carbon atoms is two. This amendment overcomes this obvious typographical error. An

identical amendment to the meanings of radicals R<sub>6</sub>, R<sub>7</sub>, R<sub>8</sub>, R<sub>9</sub>, R<sub>11</sub>, R<sub>12</sub>, R<sub>13</sub>, R<sub>14</sub>, R<sub>15</sub>, R<sub>16</sub>, R<sub>17</sub> and R<sub>18</sub> has been effectuated.

Again, it is emphasized that this amendment to the claims, as well as the specification at Page 1, line 31 to Page 2, line 12, corrects an obvious typographical error which does not involve the introduction of new matter.

The seventh ground of indefiniteness is the alleged indefiniteness of the term “heteroalkyl.” The Official Action states that there is no such thing. Applicants respectfully demur.

Attention is directed to Page 4 of the specification at lines 7-12. That paragraph indicates that alkyl encompasses cycloalkyl. As such, the meaning “heteroalkyl” merely represents a saturated ring structure in which one of the ring atoms is a heteroatom, e.g. nitrogen, oxygen, sulfur and the like. Clearly, heterocyclic alkyls are known in the art. Therefore, a heteroalkyl ring is tantamount to reciting a heterocyclic alkyl which does indeed exist. This meaning is sanctioned by an applicants’ right to be their own lexicographer.

A similar traverse is made of the eighth indefiniteness ground of rejection, the recitation of a “alkyl ring” as one of the meanings included at Page 81, line 9 of Claim 1. Again, the fact that alkyl encompasses cycloalkyl makes the term “alkyl ring” meaningful and definitive.

Insofar as a claim need only be understood by those skilled in the art, the ninth indefiniteness ground of rejection, that the ring be formed not only from the variables but also from the ring atoms to which the variables are attached, is well established in the art. As such, that amendment to Claim 1 and to the specification, at Page 3, lines 9-13, adds no new matter to the application.

Applicants respectfully traverse the eleventh predicate for the indefiniteness rejection of record, the allegation that Claims 7 and 8 are duplicates. Claim 7 is directed to a pharmaceutical composition for treating a plurality of illnesses, Claim 8 is directed to a pharmaceutical composition for treating disorders arising from deficient serotonergic neurotransmission. Applicants respectfully submit that these two claims are not of identical scope.

Claim 8 encompasses a pharmaceutical composition for treating disorders that include those recited in Claim 7. However, other disorders, not mentioned in Claim 7, are encompassed by Claim 8. As such, the scope of Claim 7 is narrower than that of Claim 8. Stated differently, the scope of diseases and disorders resulting from deficient serotonergic neurotransmission includes diseases or disorders not mentioned in Claim 7.

Applicants also traverse the twelfth and last indefiniteness ground of rejection, the alleged indefiniteness of the item “drug abuse” in Claim 9. The term “drug abuse” is well understood by those skilled in the art. It is axiomatic that a term is given its broadest reasonable interpretation consistent with the specification. In re Morris, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). Those skilled in the art appreciate that the term “drug abuse” infers abuse of habit forming controlled substances. Thus, although moderate use of marihuana may be within the scope of the objected to term, depending upon the habitual nature of that use, tobacco, which is not a controlled substance, and steroids, which are not habit forming, are not within the contemplation of that term. In summary, the term “drug abuse” is well understood by those skilled in the drug addict treatment arts to which that term in Claim 9 of the present application is addressed. Therefore, the term adds no indefiniteness to Claim 9.

Claim 10 has been separately rejected, under 35 U.S.C. §112, second paragraph, as being indefinite. The basis for this indefiniteness ground of rejection is the alleged absence of a clear definition of disorders within the scope of “deficient serotonergic neurotransmission.”

The test of the definitiveness of a term in a claim is whether the claim has a well understood meaning in the art or, alternatively, is defined in the specification. Personalized Media Communications, LLC v. U.S. International Trade Commission, 161 F.3d 696, 705, 48 USPQ2d 1880, 1888 (Fed. Cir. 1998). Clearly, the term “deficient serotonergic neurotransmission” is well known in the art and is furthermore defined by well understood disorders resulting from this condition. Attention is directed to the specification, at Page 6, lines 29-35, wherein conditions arising from deficient serotonergic neurotransmission are set forth. Indeed, the arguments made in support of this ground of rejection do not include imprecision in language. If there is merit to this ground of rejection it resides in the sufficiency of the written description to enable the practice of the invention of the claims, which is a ground of invalidity under 35 U.S.C. §112, first paragraph. In re Borkowski, 422 F.2d 905, 909, 164 USPQ 642, 645-46 (CCPA 1970).

Indeed, Claim 10 is also subject to rejection, under 35 U.S.C. §112, first paragraph, as containing subject matter not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most merely connected, to make and/or use the invention. The Official Action avers that the compounds employed in the method of Claim 10 are disclosed in the specification to be active at receptor 5-HT<sub>1</sub>. The Official Action avers that there are five 5-HT<sub>1</sub> receptors and many other serotonergic neurotransmission receptors in the body. The Official Action argues that diseases that are regulated by these receptors would not be expected to be affected by these compounds since

these compounds are not disclosed to be active at these sites. Yet such disorders would fall within the ambit of Claim 10.

The test of satisfaction of the requirements of §112 ¶1 is that the claim enables one skilled in the art to practice the invention. Those skilled in the art are aware that serotonergic neurotransmission is enhanced by treatment with ligands having high affinity for the 5-HT<sub>1</sub> receptors. This teaching is made in the specification at Page 1, lines 27-29. That there are other receptors, in addition to the 5HT<sub>1</sub> receptors, is irrelevant to the disclosure. It is only diseases that result from deficient serotonergic neurotransmission that are within the scope of Claim 10. There is nothing in Claim 10 that suggests disorders other than those within the definition of deficient serotonergic neurotransmission which, in the specification, is defined as those diseases that result from insufficient transmission of serotonin to 5-HT<sub>1</sub> receptors. As such, the rejection of Claim 10, under 35 U.S.C. §112, first paragraph, is without merit insofar as the specification enables those skilled in the art to practice the invention as set forth in the specification.

The final ground of formal rejection imposed in the outstanding Official Action is directed to Claims 9 and 10. These claims stand rejected, under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement.

The predicate for this rejection is that claims are deemed not enabled based on the failure of these claims to meet the test of enablement set forth In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

It is generally agreed that the crux of the Wands criteria for enablement resides in the degree of experimentation required to practice the invention. Consistent with this test is the conclusion that a patent specification is enabling even though it lists elements that could form



thousand of end products some of which may not be operative. E.I. duPont de Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984).

So it is in the present application. A method for treating disorders associated with deficient serotonergic neurotransmission by utilization of compounds within the scope of formula I are set forth. This teaching permits treatment of these disorders in a reasonable matter given the disclosure of a large number of preferred embodiments exemplified in the specification which overcome the disorders associated with deficient serotonergic neurotransmission. Applicants, therefore, strongly submit that enablement of Claims 9 and 10 is met by the specification disclosure of the present application.

Two of the claims, Claims 6 and 11, submitted for examination are subject to objection. Applicants submit that there is no basis for objection to Claim 11. Claim 11 is an independent claim for which no grounds of rejection have been advanced in the outstanding Official Action. Therefore, Claim 11, with the removal of subject matter finally restricted out of the application, is in condition for allowance.

As far as Claim 6 is concerned, that claim stands objected to, presumably based on its dependency from Claim 1, which has been made subject to rejection, supra. Claim 6 recites fourteen compounds within the contemplation of the compound of Claim 1, from which Claim 6 depends. However, the above remarks establish that Claim 1 is itself patentable. As such, Claim 6 is also in condition for allowance.

The above amendment and remarks establish the patentable nature of all the claims currently in this application. Notice of Allowance and passage to issue of these claims,

Claims 1, 2, 5, 6 and 7-11, is therefore respectfully solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Marvin Bressler", with a long horizontal flourish extending to the right.

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